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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/440,384	11/15/1999	HOWARD A. KINGSFORD	05918-153001	2883

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EXAMINER

PATTERSON, MARC A

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/440,384

Applicant(s)

KINGSFORD, HOWARD A.

Examiner

Marc A Patterson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>30</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

This action is intended to replace the Office Action of January 29, 2004.

Election/Restrictions

1. Newly submitted claims 24 – 34 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly submitted claims are directed to a method of making a skin attachment member, rather than to a skin attachment member.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 24 – 34 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

WITHDRAWN REJECTIONS

2. The 35 U.S.C. 112 second paragraph rejection of Claim 19, of record on page 2 of the previous Action, is withdrawn.

NEW REJECTIONS

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 2 – 12 and 16 – 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Reed et al. (U.S. Patent No. 5,312,456).

With regard to Claim 19, Reed et al. disclose an array (plurality; column 3, lines 7 – 9) of surfaces having a pointed shape (therefore a tip; column 3, lines 14 – 17) which is used to pierce and therefore penetrate, skin (column 4, lines 28 – 32) formed of plastic (column 3, lines 40 – 42); the skin attachment member is therefore a skin attachment member of plastic resin, and is configured to penetrate into the epidermal skin layer; the skin attachment has a sheet form backing from which the penetrating elements extend integrally (base; column 7, lines 26 – 27), and is used as a bandage (column 5, lines 21 – 26); the skin penetrating elements include a retention barb extending from an outer surface of the skin penetrating element (a barb which bonds with skin; column 4, lines 28 – 34); the skin penetrating elements are integral with the backing, and is therefore formed integrally (column 3, lines 32 – 34); the plastic comprises a single plastic resin (polysulphone; column 3, lines 44 – 45).

With regard to Claim 4, the surfaces of the skin penetrating elements have pointed shapes (column 3, lines 16 – 22; column 60 – 66), and therefore, pointed tips.

With regard to Claim 10, each skin penetrating element includes two barbs (column 3, lines 60 – 66, Figure 6).

With regard to Claim 16, the scope of the claim falls within the limitation of Reed et al. as discussed above. The process of making the skin attachment member (product – by – process) is given little patentable weight. Applicant would need to demonstrate, by verified showing, the unexpected advantages accruing from making the elements by molding as claimed.

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With regard to Claim 17, the skin penetrating elements have pointed shapes, and therefore define depressions on the surface.

With regard to Claim 20, as stated previously, the penetrating element has a pointed shape; it therefore tapers continuously from the base to the tip.

With regard to Claim 21, Reed et al disclose barbs having a length ranging from 4 – 18 μm high (column 6, lines 11 – 28); the claimed aspect of the skin penetrating elements being disposed at different distances from the backing therefore reads on Reed et al.

With regard to Claim 23, as stated previously, the barb extends from the outer surface of the penetrating element; it therefore has a lower surface disposed substantially perpendicular to a central axis of the skin penetrating element from which it extends.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2 – 3, 5 – 9, 11 – 12 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456)..

With regard to Claims 2 – 3 and 22, Reed et al. fail to disclose a skin penetrating element comprising a cone – shaped body having a diameter of about 0.003.” However, Reed et al disclose a pointed solid triangular body having a width of 4 – 18 μm (column 6, lines 11 – 28). It

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would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a skin penetrating element comprising a cone – shaped body having a diameter of about 0.003,” since the modification would have involved a mere change in shape. A change in shape is generally recognized as being within the level of ordinary skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

With regard to Claims 5 – 9, 11 – 12 and 18, Reed et al. fail to disclose a skin penetrating element having a diameter of 0.003”, and a skin penetrating element having a length of 0.012” and a backing having a thickness of 0.003 to 0.008”, and a retention barb which is 0.008” to 0.0095” from the backing, and a retention barb with a length of 0.0001”, and a retention barb which tapers from a thickness of 0.0001” to a point at an angle of 72 degrees, and a skin attachment member having a density of 400 skin penetrating elements in a 0.1 in² area and the elements are spaced apart from each other a distance of 0.003 inches, and the elements perpendicular to the backing. However, Reed et al disclose a skin penetrating element having a diameter of greater than 0.1 μm (column 6, lines 61 – 65), and a skin penetrating element having a length of 4 – 18 μm long (therefore 4 – 18 μm from the backing; column 6, lines 11 – 28) and a backing having a thickness of at least a fraction of 1 μm (the element comprises a backing; column 3, lines 32 – 34), and a retention barb with a length of 12 μm, and a retention barb which tapers from a thickness of 0.1 μm to a point at an angle of at least 1 degree from the thickness to a pointed piercing barb, and a skin attachment member having a density of 200,000 skin penetrating elements in a 1 cm² area (column 6, lines 61 – 65) and the elements are spaced apart from each other a distance of at 4 – 18 mm (column 6, lines 11 – 28) and teaches that maximum flexibility is desired (column 4, lines 47 – 48). Therefore, one of ordinary skill in the art would

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recognize the advantage of varying the diameter, length and angle of point of the penetrating element, the thickness of the backing and the number of elements per area to obtain a desired range of flexibility. Therefore, the flexibility would be readily determined through routine optimization of diameter, length and angle of point of the penetrating element, the thickness of the backing and the number of elements per area by one having ordinary skill in the art depending on the desired end use of the product.

It therefore would be obvious for one of ordinary skill in the art to vary the diameter, length and angle of point of the penetrating element, the thickness of the backing and the number of elements per area in order to obtain a desired flexibility, since the flexibility would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Reed et al, in the absence of unexpected results.

through routine optimization by one having ordinary skill in the art depending on the desired end use of the product. It therefore would be obvious for one of ordinary skill in the art to vary the diameter, length and angle of point of the penetrating element, the thickness of the backing and the number of elements per area, since the diameter, length and angle of point of the penetrating element, the thickness of the backing and the number of elements per area would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Reed et al.

7. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456) in view of Fye (U.S. Patent No. 5,031,609).

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Reed et al disclose a skin – attachment member as discussed above. With regard to Claim 13, Reed et al. fail to disclose a skin attachment member comprising nylon.

Fye teaches the use of nylon in the making of bandages, for the purpose of making bandages which are light – weight and hand – washable (column 2, lines 34 – 39).

Since Reed et al and Fye, both, teach fastening to skin (column 5, lines 21 – 26 of Reed et al; column 2, lines 34 – 39 of Fye) one of ordinary skill in the art would have recognized the advantage of providing for the nylon of Fye in the skin attachment member of Reed et al, depending on the desired weight and hand – washability of the end product as taught by Reed et al.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for nylon in Reed et al. in order to obtain bandages which are light – weight and hand – washable as taught by Fye.

8. Claims 14 – 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456) in view of Coates (U.S. Patent No. 4,219,019).

Reed et al disclose a skin – attachment member as discussed above. With regard to Claims 14 and 15, Reed et al. fail to disclose a skin attachment member comprising polyethylene terephthalate.

Coates teaches that polyethylene terephthalate is notoriously well known in the art in the making of bandages (column 5, lines 14 – 19), since polyethylene terephthalate possesses bulk and conformability in the bandage art (column 1, lines 60 – 63). Therefore, one of ordinary skill in the art would have recognized the advantage of providing for the polyethylene terephthalate of

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Coates in Reed et al, which is a bandage, depending on the desired bulk and conformability of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for polyethylene terephthalate in Reed et al. in order to obtain bandages which possesses bulk and conformability as taught by Coates.

ANSWERS TO APPLICANT'S ARGUMENTS

9. Applicant's arguments regarding the 35 U.S.C. 112 second paragraph rejection of Claim 19, of record on page 2 of the previous Action, have been considered and have been found to be persuasive. The rejection is therefore withdrawn.

Applicant's arguments regarding the 35 U.S.C. 102(b) rejection of Claims 4, 10, 16 – 17, 19 – 20 and 23 as being anticipated by Reed et al. (U.S. Patent No. 5,312,456), 35 U.S.C. 103(a) as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456), 35 U.S.C. 103(a) rejection of Claim 13 as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456) in view of Fye (U.S. Patent No. 5,031,609), and 35 U.S.C. 103(a) rejection of Claims 14 – 15 as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456) in view of Coates (U.S. Patent No. 4,219,019), of record in the previous Action, have been considered but have not been found to be persuasive for the reasons set forth below.

Applicant argues, on page 5 of Paper No. 23, that Reed et al fails to teach an array of skin penetrating elements which is formed integrally from a single plastic resin because the etching techniques used by Reed et al could not be used to form overhanging barbs using a single plastic resin. However, as stated on page 3 of the previous Action, the skin penetrating elements

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disclosed by Reed et al are integral with the backing are made of a rigid material comprising plastic; the claimed aspect of the 'array of skin penetrating elements' being formed 'integrally from a single plastic resin' therefore reads on Reed et al.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc Patterson, whose telephone number is (571) 272 – 1497. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by phone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached at (571) 272 – 1498. FAX communications should be sent to (703) 872-9310. FAXs received after 4 P.M. will not be processed until the following business day.

Marc A. Patterson, PhD.

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HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

4/26/04